Re-evaluation Decision RVD2012-09

Ethalfluralin

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Table of Contents

Re-evaluation Decision 1
What Does Health Canada Consider When Making a Re-evaluation Decision? 1
What Is Ethalfluralin? 2
Health Considerations 2
Environmental Considerations 3
Measures to Minimize Risk 4
Other Information 4
Appendix I Comments and Responses 5
Appendix II Label Amendments for Products Containing Ethalfluralin 10

Re-evaluation Decision

After a re-evaluation of the selective preplant herbicide ethalfluralin, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing ethalfluralin for sale and use in Canada.

An evaluation of available scientific information found that products containing ethalfluralin do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of ethalfluralin uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of ethalfluralin was first presented in Proposed Re-evaluation Decision PRVD2011-16, *Ethalfluralin*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of ethalfluralin as well as summarizes the Agency's decision and the reasons for it. Comments received during the consultation process did not result in substantial changes to the proposed regulatory decision as described in PRVD2011-16 and Appendix I summarizes the comments and provides the PMRA's response. This decision is consistent with the proposed re-evaluation decision stated in PRVD2011-16. To comply with this decision, registrants of products containing ethalfluralin will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Ethalfluralin has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews, a review of the chemistry of Canadian products, as well as additional occupational risk assessments conducted during re-evaluation, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of ethalfluralin. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated ethalfluralin and published its conclusions in a 1995 RED and also conducted subsequent human health risk assessments published in 2002 and 2007 Federal Register documents.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2011-16, *Ethalfluralin*.

What Is Ethalfluralin?

Ethalfluralin is a selective preplant soil incorporated herbicide for pre-emergence control of volunteer cereals, annual grasses, and broadleaved weeds. The herbicidal activity of ethalfluralin is due to inhibition of cell division. It is registered for use on canola, field peas, yellow mustard, sunflowers, alfalfa (for establishment), coriander, fababeans, soybeans, dry common beans (white and kidney), dill, caraway, safflower, and lentils. Ethalfluralin can be applied once per year, either in the fall or in the spring prior to seeding, followed by two soil incorporations with tractor-drawn equipment. The first soil incorporation must be done within 24 hours of application and preferably simultaneously with application. The granular ethalfluralin end-use product can be applied by farm workers or custom applicators using a granular spreader. In addition, ethalfluralin can be applied by custom applicators as a blended liquid or granular fertilizer-pesticide product using groundboom equipment or granular application equipment, respectively.

Health Considerations

Can Approved Uses of Ethalfluralin Affect Human Health?

Ethalfluralin is unlikely to affect your health when used according to the revised label directions.

People could be exposed to ethalfluralin through consumption of food and water, working as a loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Ethalfluralin is unlikely to affect human health provided that risk-reduction measures required by the PMRA to further protect workers are implemented.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Ethalfluralin is currently registered in Canada and MRLs have been established at 0.05 ppm for dried dillweed leaves, dry broadbeans, dry field peas, dry kidney beans, dry lentils, dry navy beans, dry soybeans, fresh dillweed leaves, mustard seeds (condiment type), rapeseeds (canola), safflower seeds, sunflower seeds, as of 18 March 2011. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*.

Environmental Considerations

What Happens When Ethalfluralin Is Introduced Into the Environment?

Ethalfluralin is unlikely to affect non-target organisms provided that proposed mitigation measures are followed.

Terrestrial and aquatic species could be exposed to ethalfluralin in the environment. Environmental risk is assessed by the risk quotient method – the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

Ethalfluralin is unlikely to pose adverse effects to the environment if used according to amended labels. The PMRA requires improvements to environmental label statements, addition of use instructions to the manufacturing concentrate label, and aquatic and terrestrial buffer zones for blended liquid fertilizer-pesticide products containing ethalfluralin to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of ethalfluralin, the PMRA is requiring further risk-reduction measures for ethalfluralin products.

- Hazard label statements regarding skin sensitization and eye and skin irritation potential.
- Additional personal protective equipment (PPE) and engineering controls for workers.
- A 12-hour restricted-entry interval (REI).
- Improvements to environmental label statements.
- Buffer zones for application of liquid blended fertilizers to protect non-target, sensitive aquatic and terrestrial habitats.
- Addition of use instructions for ethalfluralin blended fertilizers to the manufacturing concentrate label, including the requirement for soil incorporation.
- Requirement for the fertilizer blending facilities to provide the ethalfluralin manufacturing concentrate label to the custom applicator of ethalfluralin blended fertilizers.

Appendix II lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on ethalfluralin within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Human Health Risk Assessment

1.1 Comment

Fetal effects observed in the rabbit developmental studies are not considered relevant adverse effects because they were observed in the presence of maternal toxicity. For that reason, they should not form a basis for setting the *Pest Control Products Act* factor.

PMRA Response
For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children and potential pre- and post-natal toxicity. A different factor may be determined to be appropriate based on reliable scientific data. Furthermore, as the worker population could include pregnant women, it is necessary to afford adequate protection of the fetus that may be exposed via its mother. Consequently, an additional uncertainty factor may be applied to worker exposure scenarios if available data identify concerns for potential effects on the young or if appropriate data are not available to adequately address the concerns.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the database for ethalfluralin contains the full complement of required studies, including developmental toxicity studies in rats and rabbits and a multigeneration reproductive toxicity study in rats. With respect to identified concerns relevant to the assessment of risk to infants and children, developmental effects observed in the rabbit developmental toxicity study were considered serious endpoints and when selected for risk assessment purposes, were subject to the application of the *Pest Control Products Act* factor. As concern for this endpoint was tempered by the occurrence of maternal toxicity at the same dose level, the *Pest Control Products Act* factor was reduced from 10-fold to 3-fold for residential scenarios resulting in potential in utero exposure. To address concerns for prenatal toxicity, an additional 3-fold uncertainty factor was also applied to worker exposure scenarios when an endpoint from a developmental toxicity study in rabbits was utilized for risk assessment. Details regarding a framework for the application of the *Pest Control Products Act* factor are presented in Science Policy Note SPN2008-01, *Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk assessment of Pesticides*.

1.2 Comment

Why was an oral endpoint from the rabbit developmental study used by the PMRA in the short-term dermal assessment when the rabbit 21-day dermal toxicity study was available?

PMRA Response
For hazard assessments where the critical effect demonstrated in oral studies has not been assessed in a dermal toxicity study, the PMRA considers the most relevant oral study, which has examined that critical endpoint. Since a 21-day dermal toxicity study in rabbits did not examine the critical effects observed in the rabbit developmental toxicity study, the PMRA determined that an oral endpoint from the rabbit developmental toxicity study would be utilized for short-term dermal risk assessment.

1.3 Comment

A dermal absorption factor of 2.8% should be used in both short-term and cancer occupational risk assessments.

PMRA Response
The PMRA acknowledges that the dermal absorption factor of 2.8% applies equally to occupational short-term risk assessment as it does to occupational cancer risk assessment, and has updated the occupational exposure assessment accordingly. The use of a 2.8% dermal absorption factor for short-term risk assessment did not affect risk-reduction measures required to protect the health of workers, as these are based on cancer risk estimates calculated using a 2.8% dermal absorption factor.

1.4 Comment

Why does the PMRA require a respirator for workers loading ethalfluralin products?

PMRA Response
The PMRA requirement of a respirator for workers mixing/loading ethalfluralin product was based on the cancer risk assessment conducted by the PMRA. A Lifetime Average Daily Dose (LADD) was estimated based on the Canadian default assumptions and information provided by the registrant (for example, the Canadian maximum application rate, 15-30 exposure days per year, area treated per day of 60-240 ha, working lifetime of 40 years, and expected lifespan of 75 years). Cancer risk estimates for all assessed exposure scenarios exceeded the PMRA level of concern for workers. Therefore, to mitigate the potential cancer risks, the PMRA requires additional risk-reduction measures depending on the amount of ethalfluralin handled per day. For workers handling ≤110 kg a.i. per day, coveralls over a single layer of clothing and gloves during all activities plus a respirator while mixing/loading is required. For workers handling more than 110 kg a.i. per day, in addition to the PPE specified above, a respirator or a closed cab is required during application.

1.5 Comment

A 24-hour restricted-entry interval (REI) required by the PMRA should be re-considered since soil surface incorporation/blending of the product occurs immediately after ethalfluralin application.

PMRA Response
The PMRA has reduced the required REI to12 hours based on the low potential for postapplication exposure due to soil incorporation occurring immediately after ethalfluralin application. Please refer to the revised label amendments in Appendix II.

1.6 Comment

How did the PMRA determine that the potential dietary cancer risk for the Canadian general population would be below the level of concern?

PMRA Response
The 2007 USEPA cancer risk estimate of 2×10^{-6} was based on a number of assumptions, including tolerance-level residues for many commodities, 100% of crop treated with ethalfluralin, and anticipated drinking water residues. Considering the percentage of crop treated with ethalfluralin in Canada, as well as available food residues and drinking water monitoring data indicating that the detected ethalfluralin residues were lower than values assumed in the US assessment, the PMRA determined that the US cancer risk estimate is conservative to the Canadian situation. On this basis, it was concluded that the potential cancer risk would be below the level of concern for the Canadian general population.

1.7 Comment

How can the PMRA not be concerned about chemical exposures that have a cancer risk greater than zero?

PMRA Response
When assessing risks posed by exposure to non-threshold (or presumed non-threshold) carcinogenic substances, regulatory agencies, including Health Canada, assume that any level of exposure (other than zero) is associated with some hypothetical cancer risk. The acceptability of cancer risk is a risk management decision that cannot rely exclusively on a numerical standard, but needs to take into consideration all the factors that influence the risk. That said, a lifetime cancer risk that is below 1×10^{-6} (one in a million) for the general population (first recommended by the US National Academy of Sciences, 1987) has long been considered by many regulatory agencies as a standard for negligible risk and is also used by the PMRA as a guide in reaching decisions about the acceptability of lifetime cancer risk for the Canadian population. Details regarding the current risk-based approach to the regulation of pesticides are presented in Science Policy Note SPN2000-01, *Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*.

1.8 Comment

The PMRA did not account for cumulative carcinogenic effects that result from combined exposure to multiple pesticides registered by the PMRA.

PMRA Response
The cumulative assessment of risks posed by exposure to multiple chemicals (or mixtures) pose a challenge to risk assessors as there are virtually unlimited number of combinations of chemicals – not limited to pesticides – to which the general population may be exposed. The cumulative toxicity of two or more pesticides could be expected to result in 1) dose-addition (chemicals with a similar mechanism/mode of action), 2) response-addition (chemicals with dissimilar mechanism/mode of action), or 3) interaction (any joint action that deviates from the combined toxicity described above). Currently, as per the *Pest Control Products Act* (section 7b(i)) requirements, the PMRA considers the cumulative effects of pesticides that share a common mechanism of toxicity. The conceptual framework of the process that the PMRA uses to identify pesticides that cause a common toxic effect by a common mechanism is presented in Science Policy Note SPN2001-01, *Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment*. To date, it has not been determined whether ethalfluralin shares a common mechanism of toxicity with another pesticide or produces a toxic metabolite that is also produced by other substances. Therefore, consistent with SPN2001-01, a cumulative risk assessment for ethalfluralin was not conducted by the PMRA.

1.9 Comment

The continued registration of products containing ethalfluralin is likely to cause harm to Canadians. Therefore, the Minister should use the precautionary principle as described in section 20(1) of the *Pest Control Products Act* and discontinue the registration of ethalfluralin.

Response
Ethalfluralin was evaluated under the PMRA Re-evaluation Program to determine whether it meets modern standards established to protect human health and the environment. The science-based evaluation of ethalfluralin found that pesticide products containing this active ingredient do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of continued registration, the PMRA requires new risk-reduction measures to protect human health and the environment.

2.0 Environmental Risk Assessment – Buffer Zones

2.1 Comment

In their 1997 RED for ethalfluralin, the USEPA reported two LC_{50} values for Eastern oyster, the LC_{50} of 100 and 170 parts per billion (ppb). To harmonize the PMRA and USEPA assessments, the PMRA should revise buffer zone calculations for marine/estuarine invertebrates by using the Eastern oyster LC_{50} value of 170 ppb.

PMRA Response
The PMRA considered the provided comment but did not revise the buffer zone calculation. The most sensitive Eastern oyster LC_{50} value of 100 ppb was used by the PMRA as an input for buffer zone calculation for marine/estuarine invertebrates. This is consistent with the value used by the USEPA in their environmental risk assessment.

2.2 Comment

The buffer zone statement referring to the use of hand-held or backpack sprayer or spot treatment applications/equipment should be revised since these methods are not approved for ethalfluralin applications.

PMRA Response
Based on the fact that hand-held and backpack sprayers or spot treatment are not approved for ethalfluralin application, the PMRA has revised the required label statement. Please refer to the revised label amendment in Appendix II.

Appendix II Label Amendments for Products Containing Ethalfluralin

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

TECHNICAL GRADE PRODUCT LABEL

I) The following statements must be included on the primary panel on the technical grade product label:

> POTENTIAL SKIN SENSITIZER
> DANGER - EYE AND SKIN IRRITANT

II) The following statements must be included in a section entitled **PRECAUTIONS** on the technical grade product label:

> Potential skin sensitizer.
> Causes eye and skin irritation. DO NOT get in eyes or on skin.

END-USE PRODUCT LABEL

I) The following use-site must be removed from a section entitled **CROPS REGISTERED** on the end-use product label:

> triazine tolerant canola

II) The following statement must be included on the primary panel:

> POTENTIAL SKIN SENSITIZER

III) The following statements must be included in a section entitled **PRECAUTIONS** on the end-use product label:

> Potential skin sensitizer.
>
> Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves and protective eyewear during all activities plus a respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH/MSHA/BHSE approved canister approved for pesticides while loading. In addition, when handling more than 110 kg a.i./day; (78 ha at the maximum rate of 1.4 kg a.i./ha), wear a respirator as specified above while applying or use a closed cab while applying.
>
> DO NOT enter treated areas for 12 hours following application.

IV) The following statements must be included in a section entitled **DIRECTIONS FOR USE** on the end-use product label:

> As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

V) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARD** on the end-use product label:

> Toxic to aquatic organisms.
>
> To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.
>
> Avoid application when heavy rain is forecast.
>
> Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

MANUFACTURING CONCENTRATE PRODUCT LABEL

I) The following hazard label statements must be included on the primary panel on the manufacturing concentrate product label:

> POTENTIAL SKIN SENSITIZER
> DANGER - EYE AND SKIN IRRITANT

II) The following statements must be included in a section entitled **PRECAUTIONS** on the manufacturing concentrate product label:

> Potential skin sensitizer.
> Causes eye and skin irritation. DO NOT get in eyes or on skin.
>
> Wear protective eyewear.

III) The following statement must be included in the section entitled **MANUFACTURING INSTRUCTIONS, DIRECTIONS FOR USE** on the manufacturing concentrate label after the statement "The blended fertilizer is to be custom applied":

> The manufacturer of the blended fertilizer must provide a copy of this label to the custom applicator to provide them with use instructions and precautions for application of the blended fertilizer containing ethalfluralin.

IV) The section entitled **APPLICATION** on the manufacturing concentrate label should be renamed: **APPLICATION OF BLENDED FERTILIZERS – USE INFORMATION TO BE COMMUNICATED TO CUSTOM APPLICATOR.** The following detailed information must be included in this section:

> PRECAUTIONS including hazard statements, personal protective equipment required for applicators of ethalfluralin-blended fertilizer, REI.
>
> DIRECTIONS FOR USE including weeds controlled, weeds suppressed, crops registered and application instructions for custom applicators of granular and liquid blended fertilizer.
>
> ENVIRONMENTAL HAZARD statements.

Within those sections, the following statements must be included:

> Potential skin sensitizer.
>
> Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves and protective eyewear during all activities plus a respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH/MSHA/BHSE approved canister approved for pesticides while loading (unless a closed transfer system was used for loading). In addition, when handling more than 110 kg a.i./day (76 ha at the maximum rate of 1.44 kg a.i./ha), wear a respirator as specified above while applying or use a closed cab while applying.
>
> Apply to a soil surface free of large clods and incorporate in the same operation if possible. The first incorporation must be done within 24 hours of application.
>
> DO NOT enter treated areas for 12 hours following application.
>
> Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.
>
> DO NOT apply by air.
>
> **Buffer zones for liquid blended fertilizer application:**
>
> Use of the following spray methods or equipment DO NOT require a buffer zone: granular fertilizer applications.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial Habitat
		Less than 1m	Greater than 1m	Less than 1m	Greater than 1m	
Field sprayer	Western and eastern Canadian crops	10	1	1	1	1

TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

DO NOT use to control aquatic pests. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

V) The statement for custom applicator must be replaced with the following to indicate that all use information can be found on the manufacturing concentrate label instead of the information sheet.

NOTE: Custom applicator must provide the grower with proper use information. Follow the manufacturing concentrate label for ethalfluralin-blended fertilizer for all claims, uses and management of the end use formulated product. Failure to follow the manufacturing concentrate label for ethalfluralin-blended fertilizer may result in erratic weed control and/or crop damage.